IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	No. 1:19-md-2875-RBK Hon. Robert B. Kugler Hon. Thomas I. Vanaskie

PLAINTIFFS' MEMORANDUM OF LAW
IN OPPOSITION TO ZHP'S MOTION TO SEAL

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INTRODUCTION

The Court is familiar with and has preserved the public's right to access court records in this litigation on numerous occasions. Ignoring this, and fearing public disclosure of the extent and length of its knowledge of the contamination of its valsartan with carcinogenic nitrosamines NDMA and NDEA, ZHP mischaracterizes the content of the September 20, 2021 transcript and the underlying July 27, 2017 email, neither of which contain proprietary information of any use to ZHP or its competitors. ZHP follows its usual pattern of conflating its own interest in hiding its misconduct and fraud on patients, physicians, and payors—**the fact that** [redacted] with the completely conclusory and factually unsupported assertion that its competitors may somehow improperly benefit from that information becoming public. The Court has rejected this argument repeatedly, and should do so again.

Ironically, ZHP seeks to support its motion with a declaration from Min Li, the 30(b)(6) witness who was confronted with the email at issue in his deposition—because [redacted] In his declaration, Min Li provides details about the email that he did not know when he was deposed, and **conclusory statements as to vague, imprecise harm** that will result from disclosure of its wrongdoing, none of which justifies sealing.

In addition to the obvious lack of any basis to support confidentiality, it is interesting that Min Li is now providing details purportedly based on personal knowledge when in his deposition, he testified [redacted]

[redacted]

* * *

[redacted]

(4/20/2021 Min Li Dep. Tr. 90:14-19, 90:23-91:1, Ex. A hereto). The fact that the declaration contradicts the sworn testimony is disturbing, and should result in rejection of the declaration in its entirety—or at the very least maximum skepticism as to what is asserted. The fact that ZHP would use such a transparently misleading tactic to try to hide important proof of how this public health crisis was caused demonstrates ZHP's disregard for the law or the rights of patients in the United States who were sold these dangerous, worthless pills.

What ZHP also fails to contend with is Min Li's deposition testimony confirming what the email stated, cementing the fact that [redacted] and that [redacted]. Min Li confirmed the contents of the email, including:

[redacted]

* * *

[redacted]

(4/20/2021 Min Li Dep. Tr. 87:20-88:3, 88:15-23 (emphasis added); *see also* ZHP 296, Ex. B hereto). These are all well-known public facts now—the only new part is that [redacted].

ZHP's relentless effort to characterize this email as currently proprietary, to the exclusion of the damaging information that it [redacted], is also quite hollow. The issue with contamination of sartans including valsartan and irbesartan with nitrosamines due to the quenching process is not secret, it is world news—it is the reason for the recalls, and the reason why the manufacturing processes had to be optimized. FDA, *Nitrosamines as Impurities in Drugs; Health Risk Assessment and Mitigation Workshop Day 1*, p. (Mar. 29, 2021) (stating, "**NDMA identified as a process related contaminant in Valsartan NDMA may have been present in batches reaching back to 2012 when the synthesis was changed to a process using dimethylformamide (DMF) as solvent and NaNO2 [(sodium nitrite)] as a quenching agent to destroy azide (sodium azide, used for tetrazole synthesis),"** and **"[a]ll Sartans w[]ith a tetrazole ring system synthesized by this technology expected to be contaminated"**), https://www.fda.gov/media/147331/download; 3/29/2021 Tr. of the FDA's Nitrosamines as Impurities in Drugs; Health Risk Assessment and Mitigation Workshop, 34:11-17 (stating: "[T]he change with the Sartans, the change in the production process to a solvent, dimethylformamide, which of course then can react with nitrite that has been used to quench and destroy the azide that had been used to speed up the tetrazole ring. This then was the cause to form dimethylnitrosamine," which is another name for NDMA), https://www.fda.gov/media/150681/download; FDA, *Nitrosamines as Impurities in Drugs—Health Risk Assessment and Mitigation Public Workshop*, p. 22-23 (Mar. 29-30, 2021) (stating: "For valsartan the issue was the solvent, dimethylformamide, which was heated to high

temperatures, promoting formation of dimethylamine. The latter underwent a quenching reaction in the presence of nitrite, which was added for a different purpose, leading to formation of NDMA. Therefore, this was a side reaction of a side reaction, not direct contamination of the DS or DP"), https://www.fda.gov/media/150932/download; ***see also* ZHP's Patent for Improved Method For Preparing Tetrazole For Valsartan (acknowledging its use of dimethylformamide (DMF) and sodium nitrite quenching in its manufacture of valsartan)**, https://patents.google.com/patent/CN104045602A/en. The manufacturing processes have already been scrutinized and changed. The assertion that disclosure of this information merits confidentiality, years after it is already an accepted fact worldwide that the manufacturing process must be optimized to prevent the formation of NDMA and other nitrosamines including irbesartan, has zero validity—and frankly is frivolous in light of the established public record on the issue.

It is clear that in addition to the complete lack of any substantive basis to maintain confidentiality of this document, the public's interest in understanding the timeline of when the cause and existence of the nitrosamine contamination was known to ZHP far outweighs any self-serving desire ZHP may have in shielding its misconduct from the sun's disinfecting rays.[1] This motion as to a document the contents of which ZHP has already waived confidentiality, which speaks to the core issues in the litigation, is nothing more than a desperate attempt at damage control, trying to preserve the disturbingly false narrative that [redacted]

[1] ZHP's proposed order admits that the July 27, 2017 email is subject to the Parties' briefing on its waiver of numerous confidentiality designations, and Plaintiffs even briefed the confidentiality of this email in the alternative. (ECF 1584-3, p. 6 n.1; ECF 1392). That issue is due to be decided before this new motion. However, the proposed order somehow envisions the Court deciding this motion to seal before it decides whether ZHP waived the confidentiality of the email that underlies its redactions of the September 10, 2021 transcript. That would be a waste of the Court's resources. An order confirming ZHP's waiver of certain confidentiality designations, including as to the July 27, 2017 email, will moot this motion. But in either case the substantive merits require disclosure.

There is nothing of any proprietary value to that email, and the information cannot be shielded from public access.

LEGAL ARGUMENT

I.

THE COURT SHOULD DENY ZHP'S MOTION TO REDACT THE SEPTEMBER 10, 2021 TRANSCRIPT, WHICH DOES NOT MERIT CONFIDENTIALITY AND CONTAINS VITAL HEALTH AND SAFETY INFORMATION

"[I]n cases involving large-scale discovery, the court may construct a broad umbrella protective order upon a threshold showing by the movant of good cause." *In re Avandia Mktg., Sales, and Prods. Liab. Litig.*, 924 F.3d 662, 671 n.5 (3d Cir. 2019) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 n.17 (3d Cir. 1994)). "However, Courts must be vigilant to assure Confidentiality Orders are not overused and are only used for legitimate purposes." *In re: Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Products Liability Litigation*, 512 F. Supp. 3d 546, 550 (D.N.J. 2021). This Court has previously noted that "**the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery**." *Id.* (emphasis added).

Thus, when a party challenges a designation under an umbrella protective order, "the party seeking to maintain the seal must justify the continued sealing of those documents." *Avandia*, 23 F. 3d at 671 n.5 (quoting *Pansy*, 23 F.3d at 787 n.17). "In *Pansy v. Stroudsburg*, 23 F. 3d 772 (3rd Cir. 1994), the court expounded on the burden to justify confidentiality." *Valsartan*, 512 F. Supp. 3d at 550. There, the Third Circuit set forth seven factors to consider when deciding a motion to seal or redact:

1. whether disclosure will violate any privacy interests;

> 2. whether the information is being sought for a legitimate purpose or for an improper purpose;
>
> 3. whether disclosure of the information will cause a party embarrassment;
>
> 4. **whether confidentiality is being sought over information important to public health and safety**;
>
> 5. whether the sharing of information among litigants will promote fairness and efficiency;
>
> 6. whether a party benefitting from the order of confidentiality is a public entity or official; and
>
> 7. **whether the case involves issues important to the public**.

Avandia, 924 F.3d at 671 (emphasis added) (quoting *Glenmede Tr. Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995) (citing *Pansy*, 23 F.3d at 787-91)); *see also* ECF 1269, p. 6-7. In *Pansy*, the Third Circuit also held that "**where it is likely that information is accessible under a relevant freedom of information law, a strong presumption exists against granting or maintaining an order of confidentiality** whose scope would prevent disclosure of that information pursuant to the relevant freedom of information law." 23 F.3d at 791; *see also* ECF 1269, p. 7. Importantly, this standard, which ZHP cannot meet – just as Torrent could not meet it – applies "when [a court] review[s] orders preserving the confidentiality of discovery materials pursuant to Federal Rule of Civil Procedure 26." *Avandia*, 924 F.3d at 670 (citing *Pansy*, 26 F.3d at 783-92); *see also* ECF 1269, p. 7. All of these factors cut against ZHP, which has the heavy burden on this motion.

"[T]he more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access." *Avandia*, 924 F.3d at 670 (emphasis added) (citing

Goldstein v. Forbes (In re Cendant Corp.), 260 F.3d 183, 192–93 (3d Cir. 2001)); *see also* ECF 1269, p. 7.

> The common law right of access "antedates the Constitution." *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d [339,] 343 [(3d Cir. 1986)]. The right of access "promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court." *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988). Public observation facilitated by the right of access "diminishes possibilities for injustice, incompetence, perjury, and fraud." *Id.* Moreover, "the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness." *Id.*

Avandia, 924 F.3d at 672. Thus, **once a document "has been filed with the court ... or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings," "a presumption of access attaches."** *Id.* (emphasis added) (quoting *In re Cendant Corp.*, 260 F.3d at 192); *see also* ECF 1269, p. 8.

"To overcome that strong presumption, the District Court must articulate 'the compelling, countervailing interests to be protected,' make 'specific findings on the record concerning the effects of disclosure,' and 'provide[ ] an opportunity for interested third parties to be heard.'" *Avandia*, 924 F.3d at 672-73 (quoting *In re Cendant Corp.*, 260 F.3d at 194); *see also* ECF 1269, p. 8. "In delineating the injury to be prevented, specificity is essential," so **"[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient.**" *Avandia*, 924 F.3d at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194) (emphasis added); *see also* ECF 1269, p. 8. In sum, **"[c]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants."** *Avandia*, 924 F.3d at 673 (emphasis added) (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)); *see also* ECF 1269, p. 8. ZHP's motion is built entirely on broad allegations of harm, nothing more.

Moreover, although some of the seven *Pansy* factors are relevant to a court's analysis under the common law standard, two are explicitly not considered. *Avandia*, 924 F.3d at 677. First, the Third Circuit has "repeatedly said that **concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access**." *Id.* (emphasis added) (collecting cases). Second, "a person's motive for inspecting or copying judicial records is irrelevant under the common law right of access." *Id.* at 677.

In considering the remaining five factors, the Third Circuit has put its "thumb on the scale in favor of openness—the strong presumption of public access[:]"

> **[T]he public's right of access must be the starting point, not just one of multiple factors.** The scale is tipped at the outset in favor of access. And the right of access is not a mere formality—it "promotes public confidence in the judicial system"; "diminishes possibilities for injustice, incompetence, perjury, and fraud"; and "provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness." *Littlejohn*, 851 F.2d at 678. **These interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.**

Avandia, 924 F. 3d at 677 (emphasis added).

Moreover, **"[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm."** *Id.* at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196), emphasis added. That showing cannot be made by ZHP since the contamination of its pharmaceuticals with carcinogenic nitrosamines, the cause of the contamination, and the steps taken to optimize the manufacturing processes for all sartans—including valsartan and irbesartan to prevent this from happening again—is, as established above, a matter of public record, and the failed manufacturing processes at issue are banned. Moreover, "blanket assertions of harm that 'could' come to fruition fall short of the clearly defined and serious injury that [a movant] must articulate to obtain sealing under any standard." *Avandia*, 924 F. 3d

at 679. As discussed below, ZHP fails every test, especially with regard to presumptively public documentation of the facts surrounding its wholesale contamination of trusted blood pressure drugs, which are no longer sold by ZHP in the United States.

After the Third Circuit vacated and remanded its original decision to seal the documents in *Avandia*, the trial court applied the correct standard and wrote:

> **Justice Brandeis famously declared that "sunlight is the most powerful of all disinfectants." Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents.** Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky will be denied.
>
> *In re Avandia Mktg, Sales Practices and Prods. Liab. Litig.*, 484 F. Supp. 3d 249, 268 (E.D. Pa. 2020) (emphasis added) (footnote and citations omitted).

In one of its prior confidentiality rulings in this case, the Court also noted that it "is not required to give credence to [a] conclusory self-serving affidavit that is inconsistent with the Court's independent review of [the] documents." *Valsartan*, 2512 F. Supp. 3d at 553.

In this motion, ZHP has asked the Court to seal parts of the September 10, 2021 transcript related to the July 27, 2017 email. (ECF 1584-3, ¶ 12-13).[2] Preliminarily, Plaintiffs note that ZHP's motion does not specifically analyze any of its requested redactions in its proposed order or index, and Dr. Li's declaration in support of the motion is similarly vague and inexplicably based on personal knowledge of an email that he could not recall during his deposition. (ECF

[2] ZHP's repeated efforts to maintain confidentiality of documents and information has created a massive amount of distraction and burden for the Plaintiffs and the Court and needs to be brought to an end.

1584; 4/20/2021 Min Li Dep. Tr. 90:14-19, 90:23-91:1, Ex. A hereto). ZHP's motion consequently lacks the specificity required to meet its burden. *See Avandia*, 924 F.3d at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194) (stating, "In delineating the injury to be prevented, **specificity is essential**," so **"[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient**" (emphasis added)); *see also* ECF 1269, p. 8. The Court should deny ZHP's motion for this reason alone.

Incredibly, ZHP's own proposed order granting this motion, which was filed on ECF unredacted, includes facts that it is asking the Court to redact from the transcript. (*Compare, i.e.*, ECF 1584-3, ¶ 13 (describing the July 27, 2017 email as "regarding ZHP's efforts to optimize its process for manufacturing irbesartan"), *with* ECF 1573, 10:17, 18:2-3, 19:7-9). Given the current public record, the Court cannot possibly seal this information.

Plaintiffs also note that ZHP has not moved to seal Exhibits A and B to this transcript, which contain the parts of the July 27, 2017 email that it would prefer the Court and public to focus on, as even ZHP's own witness, Min Li, admitted. (4/20/2021 Min Li Dep. Tr. 164:16-19, 165:2-9 (stating, [redacted])). This may be, in part, because the patent at issue is publicly available and thus not confidential by definition. *See* https://patents.google.com/patent/CN103613558A/en. Yet, ZHP inexplicably seeks to redact parts of the transcript concerning this publicly available patent. (*See* ECF 1573, 19:20-22, 20:3-4, 20:10-20, 22:22-33). Even if the email is actually just a commentary on this public patent, as ZHP claims, there is still no basis to seal the email or transcript either.

Nonetheless, in accordance with Third Circuit precedent, ZHP's proposed order concedes that the common law public right of access applies to this material. (ECF 1584-3, ¶ 17). *See also Avandia*, 924 F.3d at 672. In addition to "the strong presumption" against sealing these judicial

records, this Court should recognize the significant public interest in understanding the nitrosamine contamination at issue in this case as well as in the industry more broadly. *Avandia*, 924 F. 3d 677. ZHP was the first pharmaceutical manufacturer to recall its valsartan due to contamination with carcinogenic nitrosamines, and the issue is not limited to valsartan, losartan, and irbesartan, but ZHP did not disclose the contamination until its customer forced it to do so. FDA, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, https://tinyurl.com/1k9w9jid; FDA, *Information about Nitrosamine Impurities in Medications*, https://tinyurl.com/1tu3nih0. **There is an ongoing public investigation into the cause of this widespread contamination, whether it has occurred with other drugs, and how to prevent it in the future, on top of the FDA's firm determination that the contamination was wrongful and unacceptable, resulting in a complete recall and import ban against ZHP**. In fact, ZHP is still banned from importing its valsartan into the United States because it has not addressed its contamination to the satisfaction of the FDA. FDA, *Import Alert 66-40*, https://tinyurl.com/3jxjmcxc.

The July 27, 2017 email states:

[redacted]

* * *

[redacted]

* * *

[redacted]

[redacted]

(ZHP 296, Ex. B hereto, which ZHP sent to the Court following the September 10, 2021 hearing). It is public knowledge that ZHP's valsartan, losartan, and irbesartan contained carcinogenic nitrosamines. *See* FDA's Recall Announcement Regarding ZHP's Valsartan, https://tinyurl.com/pubdmu38; FDA's Recall Announcement Regarding ZHP's Losartan, https://tinyurl.com/jbpwxrk; FDA's Recall Announcement Regarding ZHP's Irbesartan, https://tinyurl.com/3eanb2sf. Moreover, it is public knowledge that the valsartan contamination was the result of ZHP quenching the API to remove sodium azide with sodium nitrite. (*See supra*, p. 3-4). Thus, the only new information in this email is [redacted]. **This is not proprietary information, it is proof of a massive fraud on thousands and thousands of people, payors, and physicians. No company would seek out this email and attempt to replicate its defective manufacturing process or [redacted]. Rather, it is Exhibit A to a cautionary tale about what happens when financial ambitions (here, to dominate the world market with cheaply manufactured valsartan) eclipse safety considerations.**

The Court has denied ZHP's motion to seal numerous other documents concerning ZHP's investigation into and knowledge of the contamination, as well as the violations of current good

manufacturing practices (cGMPs) that led to the contamination.[3] (ECF 1269). Plaintiffs note that

[redacted]. **ZHP cannot use this Court to continue to hide the information needed for a true understanding of the nitrosamine contamination of its pharmaceuticals.** *See Avandia*, 924 F. 3d at 677 (holding that "we have repeatedly said that **concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access**"); *Valsartan*, 512 F. Supp. 3d at 550 (holding that "**the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery**"). If there was ever a document that called for the disinfecting rays of the sun, it is this one. *See Avandia*, 484 F. Supp. 3d at 268.

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[3] **ZHP cites five trial court decisions, all but one of which are unpublished and unopposed, in support of its motion.** (ECF 1584-3, ¶ 21). *Impax Labs., Inc. v. Zydus Pham. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at *1 (D.N.J. Dec. 6, 2018), *Valeant Pharm. Luxembourg S.à r.l. v. Actavis Labs. UT, Inc.*, No. 2:16- cv-4344, 2018 WL 1469050, at *3 (D.N.J. Mar. 26, 2016), *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm. Inc.*, No. 1:14-cv-4727, 2015 WL 4715307, at *1 (D.N.J. Aug. 7, 2015), and *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 WL 27460 (D.N.J. Jan. 3, 2017), were all unopposed motions to seal. Mylan even wrote in support of Boehringer's motion to seal in *Boehringer*, 2015 WL 4715307, at *1. These cases do not support granting ZHP's motion here. In the fifth case—*In re Gabapentin*, 312 F. Supp.2d 653, 669 (D.N.J. 2004)—the court denied an investment research company's motion to unseal summary judgment papers filed in pharmaceutical patent holder's infringement suit against prospective manufacturers of generic version. In that case, the investment research company's entire purpose was to uncover information for the competitive benefit of others. Here, ZHP's motion attempts to prevent the public from understanding how its drug supply became contaminated with carcinogenic nitrosamines and when ZHP knew about that contamination. To the extent it contains any scientific information, the July 27, 2017 concerns manufacturing practices that neither ZHP nor its competitors could use now that their manufacturing defects are widely known and acknowledged by ZHP itself. *Gabapentin* is consequently of no import to this case.

CONCLUSION

For the foregoing reasons, the Court should deny ZHP's motion to seal. In accordance with Local Civil Rule 5.3, Plaintiffs have attached a proposed order as Exhibit C of this brief.

Dated: October 18, 2021

Respectfully Submitted,

/s/ Ruben Honik
Ruben Honik
GOLOMB & HONIK, P.C.
1835 Market Street, Ste. 2900
Philadelphia, PA 19103
Phone (215) 985-9177
rhonik@golombhonik.com

/s/ Daniel Nigh
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone (973) 228-9898
aslater@mazieslater.com

/s/ Conlee S. Whiteley
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2021, a true and correct copy of the foregoing was filed and served upon all counsel via operation of the CM/ECF system for the United States District Court for the District of New Jersey.

/s/ Adam M. Slater
Adam M. Slater